

GENERAL GOVERNMENT
Kentucky Board of Podiatry
(Amendment)

201 KAR 25:090. Prescribing and dispensing controlled substances.

RELATES TO: KRS 218A.205, 218A.172

STATUTORY AUTHORITY: KRS 218A.205(3)(a), 311.410(4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218A.205(3)(a) requires the board to establish standards for prescribing controlled substances. KRS 218A.172 requires the board to promulgate administrative regulations governing the prescribing or dispensing of any Schedule II controlled substance or a Schedule III controlled substance containing hydrocodone. KRS 218A.205(3)(b) requires the board to establish standards for prescribing a Schedule II controlled substance for more than a three (3) day supply if the prescription is intended to treat pain as an acute medical condition. This administrative regulation establishes the standards for prescribing or dispensing controlled substances.

Section 1. Prescribing or dispensing a controlled substance. (1) This administrative regulation governs the prescribing and dispensing of controlled substances listed in Schedule II through V as classified in KRS 218A.060, 218A.070, 218A.080, 218A.090, 218A.100, 218A.110, 218A.120, and 218A.130.

(2) If initially prescribing or dispensing a controlled substance, a licensee shall:

(a) Obtain a complete medical history and conduct a physical examination of the patient;

(b) Complete a written treatment plan which states the objectives of the treatment underlying the prescription of the controlled substance and which includes an outline of any further diagnostic examinations that may be required;

(c) Discuss the risks and benefits of the use of controlled substances with the patient or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence;

(d) Verify that the patient is the person that he or she has identified himself or herself as being by requiring the person to produce proper government issued identification;

(e) Query the Kentucky All-Schedule Prescription Electronic Reporting System (KASPER) for all information available on the patient if prescribing controlled substances that are included in:

1. Schedule II;
2. Schedule III; and
3. The following from Schedule IV:
 - a. Ambien;
 - b. Anorexics;
 - c. Ativan;
 - d. Klonopin;
 - e. Librium;
 - f. Nubain;
 - g. Oxazepam;
 - h. Phentermine;
 - i. Soma;
 - j. Stadol;
 - k. Stadol NS;
 - l. Tramadol;

- m. Valium;
- n. Versed; and
- o. Xanax;

(f) Obtain consent for the treatment from the patient in writing; and

(g) Document the patient's file as required by Section 2 of this administrative regulation.

(3) If it is necessary to continue the prescription or dispensation of a controlled substance after the initial supply is completed, a licensee shall:

(a) Conduct, at reasonable intervals under the circumstances presented, all clinically indicated steps;

(b) Review the course of treatment that he initially prepared to determine if any changes are required;

(c) Provide any new information about the course of treatment or any changes made to the patient;

(d) Query KASPER for all information available on the patient no less than once every three (3) months for all available data on the patient to review that data before issuing any new prescription or refill for the patient for controlled substance specified in subsection (2)(e) of this section; and

(e) Document the patient's file as required by Section 2 of this administrative regulation.

Section 2. Podiatric medical records for patients being prescribed controlled substances, ~~substance~~ shall include at a minimum:

(1) The patient's name;

(2) The patient's date of birth;

(3) The information concerning the patient's medical history and physical examination required by Section 1 of this administrative regulation;

(4) The podiatrist's diagnosis of the patient's condition;

(5) The procedures and treatments to be undertaken and their objectives;

(6) The date of the procedures or treatments;

(7) ~~{}~~Whether local or general anesthetics were used, including the type and the amount administered;

(8) Diagnostic, therapeutic, and laboratory results;

(9) The findings and recommendations of any other evaluations or consultations;

(10) All medications administered or prescribed by the podiatrist, including the date, type, dosage, and quantity administered or prescribed;

(11) Any post-treatment instructions from the podiatrist; and

(12) Documentation that the KASPER query required by Section 3 of this administrative regulation was completed.

Section 3. If a prescription for a controlled substance is written, a podiatrist shall:

(1) Obtain and document in the patient's podiatric medical record the information concerning the patient's medical history and physical examination required by Section 1 of this administrative regulation;

(2) Query the ~~[Kentucky All-Scheduled Prescription Electronic Reporting System]~~ ~~{}~~KASPER~~{}~~ for all available data on the patient if the controlled substance is one specified in Section 1(2)(e) of this administrative regulation and record the results of the query in the patient's record;

(3) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence; and

(4) Obtain consent for the treatment from the patient in writing.

Section 4. Dispensing Schedule II or Schedule III controlled substances containing hydrocodone. (1) A licensee shall not dispense more than a forty-eight (48) hour supply of Schedule II or Schedule III controlled substances containing hydrocodone.

(2) If a patient continues to present with pain after the initial supply has been completed and the podiatrist believes that an additional prescription for a controlled substance is medically appropriate, the podiatrist shall at a minimum:

(a) Follow the requirements of Section 1 of this administrative regulation; and

(b) Prescribe only that amount of the controlled substance that is appropriate under accepted and prevailing practice standards.

Section 5. Prescribing a Schedule II Controlled Substance. In accordance with the CDC Guideline for Prescribing Opioids for Chronic Pain published in 2016, a licensee shall not issue a prescription for a Schedule II controlled substance for more than a three (3) day supply of a Schedule II controlled substance if the prescription is intended to treat pain as an acute medical condition, with the following exceptions:

(1) The licensee, in his or her professional judgment, believes that more than a three (3) day supply of a Schedule II controlled substance is medically necessary to treat the patient's pain as an acute medical condition and lack of alternative treatment options which justifies deviation from the three (3) day supply limit established in this subsection in the patient's medical records;

(2) The prescription for a Schedule II controlled substance is prescribed to treat chronic pain;

(3) The prescription for a Schedule II controlled substance is prescribed to treat pain associated with a valid cancer diagnosis;

(4) The prescription for a Schedule II controlled substance is prescribed to treat pain as part of a hospice or end-of-life treatment;

(5) The prescription for a Schedule II controlled substance is prescribed as part of a narcotic treatment program, licensed by the Cabinet for Health and Family Services;

(6) The prescription for a Schedule II controlled substance is prescribed to treat pain following a major surgery or the treatment of significant trauma, as defined by the state licensing board in consultation with the Kentucky Office of Drug Control Policy;

(7) The Schedule II controlled substance is dispensed or administered directly to an ultimate user in an inpatient setting; or

(8) Any additional treatment scenario deemed medically necessary by the state licensing board in consultation with the Kentucky Office of Drug Control Policy.

Section 6. Authority to Prescribe Controlled Substances. (1) A podiatrist licensed by the board may prescribe any medicine necessary for the treatment of a patient that comes within the practice of podiatry as defined by KRS 311.380(2), including Schedule II and Schedule III controlled substances containing hydrocodone, if the licensee:

(a) Has obtained a license number from the Drug Enforcement Administration;

(b) Registers with and utilizes the ~~[Kentucky All-Schedule Prescription Electronic Reporting System (KASPER)]~~ as required by KRS 218A.202;

(c) Follows the requirements of this administrative regulation; and

(d) Meets all the requirements for utilizing KASPER promulgated by the Cabinet as well as the requirements set forth in KRS 218A.202.

(2) A licensed podiatrist shall not prescribe or dispense:

- (a) With the intent or knowledge that a medication will be used or is likely to be used for any purpose other than one that is necessary for medical treatment or therapeutic use;
 - (b) With the intent to evade any law governing the sale, use, or disposition of the medication;
 - (c) When the licensee knows or has reason to know that the abuse of the controlled substance is occurring or may result therefrom; and
 - (d) In amounts that the licensee knows or has reason to know, under the circumstance, that the amount prescribed is excessive under accepted and prevailing practice standards.
- (3) After a hearing conducted under KRS Chapter 13B and 201 KAR 25:051, the board shall fine a licensee who otherwise has the authority to prescribe controlled substances, but who has failed to register for an account with KASPER, an amount not less than \$250 per prescription for each prescription that individual has written while not properly registered.

ANN FARRER, DPM, President

APPROVED BY AGENCY: December 15, 2017

FILED WITH LRC: December 15, 2017 at 11 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on January 24, 2018 at 10:00 AM Eastern Time at the Office of the Attorney General, 1024 Capital Drive, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. This hearing is open to the public. Any person who wished to be heard will be given an opportunity to comment on the proposed regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until end of day on January 31, 2018. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Shan Dutta, Board Counsel, Asst. Attorney General, Office of the Attorney General, 1024 Capital Drive, Frankfort, Kentucky 40601, phone (502) 696-5300, fax (502) 564-6801, email Shan.Dutta@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Shan Dutta

(1) Provide a brief summary of: This administrative regulation requires all licensed podiatrists to

(a) What this administrative regulation does: This administrative regulation establishes the professional standards for licensed podiatrists for prescribing and dispensing controlled substances in the Commonwealth of Kentucky.

(b) The necessity of this administrative regulation: These changes are necessary under KRS 218A.205, that the Podiatry Board promulgate a regulation establishing professional standards for prescribing and dispensing controlled substances.

(c) How this administrative regulation conforms to the content of the authorizing statutes: The regulation updates and amends the mandatory prescribing and dispensing standards related to controlled substances.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This amendment is necessary to establish the prescribing and dispensing standards for controlled substances for licensed podiatrists per statutory requirement.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This regulation sets forth the professional standards for prescribing and dispensing opioids, as well as, the professional standard of a 3-day prescribing limit on Schedule II controlled substances for acute pain in conformity with the 2017 General Assembly's enactment of HB 333.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary because it establishes prescribing and dispensing standards per KRS 218A.205.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment is consistent with KRS 218A.205.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will provide Schedule II controlled substance prescribing standards and requirements for practicing podiatrists in the Commonwealth of Kentucky.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Approximately 200 Licensees.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: This amendment will provide the mandatory prescribing and dispensing standards and CDC Guideline for Prescribing Opioids for Chronic Pain per HB333 and KRS 218A.205.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional cost to licensees and associates.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The applicants for licensure as a podiatrist will continue to have their profession regulated by the Kentucky Board of Podiatry.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: No additional cost.

(b) On a continuing basis: No additional cost.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The board's operation is funded by the registration fees paid by licensees and applicants.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees is necessary to implement this regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: The regulation does not establish or increase fees.

(9) TIERING: Is tiering applied? Tiering was not applied as the criteria apply to all licensees.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Podiatry.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 218A.205, 311.420.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. Expenditures will not be affected by this amendment.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No additional revenue will be generated.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? N/A

(c) How much will it cost to administer this program for the first year? N/A

(d) How much will it cost to administer this program for subsequent years? N/A

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): N/A

Expenditures (+/-): N/A

Other/Explanation: N/A